



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-0556]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Assisted Reproductive Technology (ART) Program Reporting System" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 12, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System
(OMB Control No. 0920-0556, Exp. 8/31/2021) - Revision -
National Center for Chronic Disease Prevention and Health
Promotion (NCCDPHP), Centers for Disease Control and Prevention
(CDC).

Background and Brief Description

Section 2(a) of Pub. L. 102-493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a-1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention: (1) pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program, and whether the laboratory is certified or has applied for such certification under the Act. The required information is currently reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART) Program Reporting System (OMB Control No. 0920-0556, Exp. 8/31/2021). CDC seeks to continue OMB approval for a period of three years. The revised total burden estimate is higher than the previous approval, due to an increase in the utilization of ART in the United States.

The estimated number of respondents (ART programs or clinics) is 456, based on the number of clinics that provided

information in 2018; the estimated average number of responses (ART cycles) per respondent is 670. Additionally, approximately 5-10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70 cycles each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 50% of ART programs will participate in the feedback survey.

The collection of ART cycle information allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years and there are no costs to respondents other than their time. The total estimated annualized burden is 219,904 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
ART Clinics	NASS Reporting Form	456	670	43/60
	Data Validation	35	70	23/60
	Feedback	255	1	2/60

	Survey			
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